

Claim Summary:

1. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion is homogeneous; comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said drug being molecularly dispersed and amorphous in said dispersion; comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%; provides a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug; and has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

2. (canceled)

3. (canceled)

4. (original) A composition as defined in claim 1, wherein said drug is amorphous when undispersed.

5. (original) A composition as defined in claim 1, wherein said use environment is the gastrointestinal tract.

6. (original) A composition as defined in claim 1, wherein said use environment is MFD.

7. (currently amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion is homogeneous; comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said drug being molecularly dispersed and amorphous in said dispersion;

comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;

exhibits a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug; and

has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

8. (canceled)

9. (canceled)

10. (original) A composition as defined in claim 7, wherein said drug is amorphous when undispersed.

11. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;

comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said drug being molecularly dispersed and amorphous in said dispersion;

comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;

effects, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and

has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

12. (canceled)

13. (original) A composition as defined in claim 11, wherein said drug is amorphous when undispersed.

14. (canceled)

15. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;
comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said drug being molecularly dispersed and amorphous in said dispersion;
comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;
effects, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

16. (canceled)

17. (original) A composition as defined in claim 15, wherein said drug is amorphous when undispersed.

18. (canceled)

19. (canceled)

20. (canceled)

21. (canceled)

22. (original) A composition as defined in claim 1, wherein the concentration of drug in MFD falls to no less than 25% of the maximum supersaturated concentration during the 15 minutes following the time at which the maximum supersaturated concentration is reached.

23. (original) A composition as defined in claim 1, wherein said dispersion is in the form of particles less than 100 μm in diameter.

24. (original) A composition as defined in claim 7, wherein said dispersion is in the form of particles less than 100 μm in diameter.

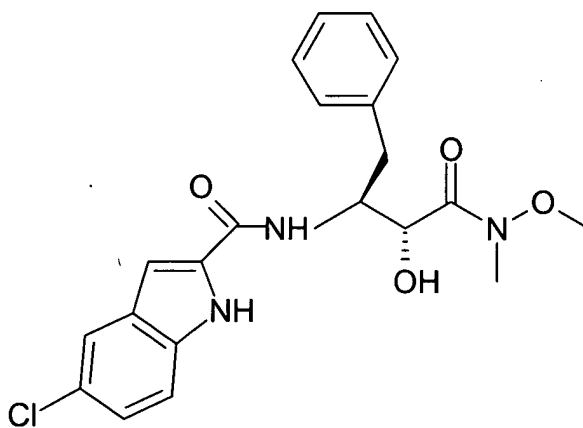
25. (original) A composition as defined in claim 11, wherein said dispersion is in the form of particles less than 100 μm in diameter.

26. (original) A composition as defined in claim 15, wherein said dispersion is in the form of particles less than 100 μm in diameter.

27. (canceled)

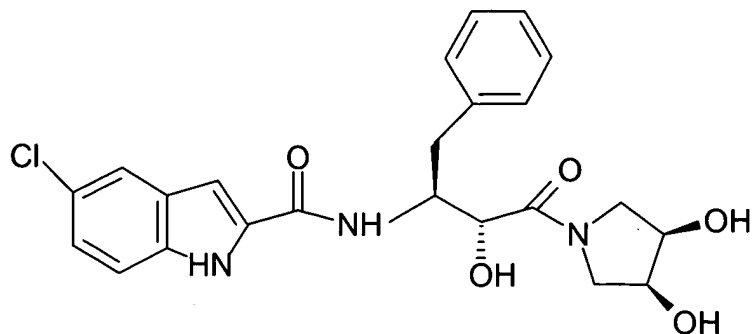
28. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug is a glycogen phosphorylase inhibitor.

29. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

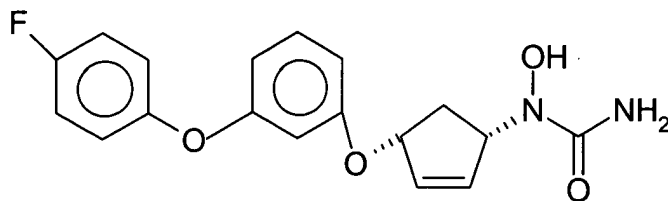
30. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

31. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug is a 5-lipoxygenase inhibitor.

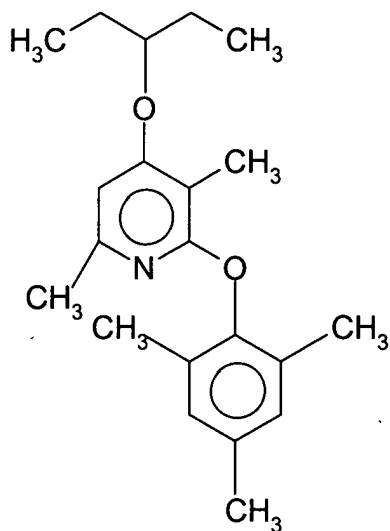
32. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

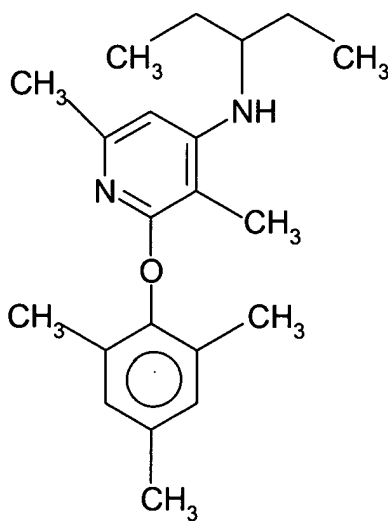
33. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is a corticotrophic releasing hormone (CRH) inhibitor.

34. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is



or a pharmaceutically acceptable salt thereof.

35. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is



or a pharmaceutically acceptable salt thereof.

36. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is an antipsychotic.

37. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is ziprasidone.

38. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is selected from griseofulvin, nifedipine, and phenytoin.

39. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion
is homogeneous;
comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;
comprises a sparingly water-soluble drug that is crystalline when undispersed, that is molecularly dispersed and amorphous in said dispersion, and that has a dose to aqueous solubility ratio greater than 100 mL, and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said dispersion providing a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

40. (canceled)

41. (previously presented) A composition as defined in claim 39, wherein said use environment is the gastrointestinal tract.

42. (previously presented) A composition as defined in claim 39, wherein said use environment is MFD.

43. (currently amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion
is homogeneous;
comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;
comprises a sparingly water-soluble drug that is crystalline when undispersed, that is molecularly dispersed and amorphous in said dispersion, and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion exhibiting a

maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug; and

has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

44. (canceled) A composition as defined in claim 43, wherein said drug has a dose to aqueous solubility ratio greater than 100.

45. (currently amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion

is homogeneous;

comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;

comprises a sparingly water-soluble drug that is crystalline when undispersed, that is molecularly dispersed and amorphous in said dispersion, and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and

has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

46. (canceled)

47. (previously presented) A composition of matter comprising a spray dried solid dispersion, which dispersion

is homogeneous;

comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;

comprises a sparingly water-soluble drug that is crystalline when undispersed, that is molecularly dispersed and amorphous in said dispersion, and that has a dose to aqueous solubility ratio greater than 100 mL, and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25

relative to a control composition comprising an equivalent quantity of undispersed drug;
and

has a drug:polymer weight ratio of ~~1 to 0.2 to 1 to 100~~ between 1:0.5 and 1:100.

48. (canceled)

49. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45 or 47 wherein said particles are solidified in less than 2 seconds.

50. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45 or 47 wherein said particles have a residual solvent content less than 2 wt%.

51. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45 or 47 wherein said particles are spray-dried from a solution in which the concentration of drug in the solvent is less than 20g/100g and in which the total solids content is less than 25 weight %.

52. (previously presented) A composition as defined in claims 1, 7, 11, 15, 39, 43, 45, or 47 wherein said drug:polymer weight ratio is greater than 1 to 20 and less than 1 to 0.4.